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Interventions to prevent occupational noise-induced hearing loss: A Cochrane systematic review

Jos H. Verbeek^{*}, Erik Kateman[†], Thais C. Morata[‡], Wouter A. Dreschler[#], and Christina Mischke^{*}

*Cochrane Occupational Safety and Health Review Group, Finnish Institute of Occupational Health, Kuopio, Finland †Aspen, Oss, Netherlands ‡National Institute for Occupational Safety and Health (NIOSH), Cincinnati, USA #Clinical & Experimental Audiology, Academic Medical Centre, Amsterdam, Netherlands

Abstract

Objective—To assess the effectiveness of interventions for preventing occupational noise exposure or hearing loss compared to no intervention or alternative interventions.

Design—We searched biomedical databases up to 25 January 2012 for randomized controlled trials (RCT), controlled before-after studies and interrupted time-series of hearing loss prevention among workers exposed to noise.

Study sample—We included 19 studies with 82 794 participants evaluating effects of hearing loss prevention programs (HLPP). The overall quality of studies was low to very low, as rated using the GRADE approach.

Results—One study of stricter legislation showed a favorable effect on noise levels. Three studies, of which two RCTs, did not find an effect of a HLPP. Four studies showed that better use of hearing protection devices in HLPPs decreased the risk of hearing loss. In four other studies, workers in a HLPP still had a 0.5 dB greater hearing loss at 4 kHz (95% CI – 0.5 to 1.7) than non-exposed workers. In two similar studies there was a substantial risk of hearing loss in spite of a HLPP.

Conclusions—Stricter enforcement of legislation and better implementation of HLPPs can reduce noise levels in workplaces. Better evaluations of technical interventions and long-term effects are needed.

Keywords

| Noise; hea | aring conservation; demographics/epidemiology; behavioral measures | |
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Correspondence: Jos H. Verbeek, Cochrane Occupational Safety and Health Review Group, Finnish Institute of Occupational Health, PO Box 310, 70101 Kuopio, Finland. jos.verbeek@ttl.fi.

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Noise is a prevalent exposure in many workplaces. Worldwide, 16% of disabling hearing loss in adults is attributed to occupational noise. Noise-induced hearing loss is the second most common self-reported occupational illness or injury, despite decades of study, workplace interventions, and regulations (Nelson et al, 2005). Exposure is especially prevalent in mining, manufacturing, and the construction industry (Tak, 2009). Construction workers are still considered as an underserved population where it comes to hearing loss prevention with one in twenty construction workers estimated to have occupational hearing loss (Suter, 2009; Tak, 2009).

Long-term exposure to noise levels beyond 80 dB(A) carries an increased risk of hearing loss, which increases with the noise level and will ultimately lead to hearing impairment. The risk of hearing impairment also increases substantially with age. There are various definitions of hearing impairment in use. The most commonly used definition for hearing impairment is a weighted average hearing loss at 1, 2, 3, and 4 kHz greater than 25 dB (John et al, 2012). Such a hearing loss decreases the capacity to engage in conversation in meetings or social activities thus creating a significant barrier in establishing or maintaining emotional relationships. Measured this way, the probability of hearing impairment occurring in persons not exposed to noise at the ages of 35 and 65 is estimated to be 10% and 55% respectively, because it increases naturally with age. Ten years of noise exposure at the level of 100 dB(A) will raise the probability of hearing impairment for the same individuals to 94.5% and 99.5%. Thus, 10 years of noise exposure entails a relative risk of hearing impairment of 9.9 for a 35 year-old worker and 1.8 for a 65 year-old worker compared to their non-exposed peers (Prince et al, 1997).

The condition is permanent and there is no current effective treatment to regenerate damaged sensory receptors after noise exposure, leaving amplification as one of the only options. However, the risk of noise-induced hearing loss can be greatly minimized if noise is reduced to below 80 dB(A) (ISO 2013).

The preventive potential of reducing noise exposure has led to mandatory hearing loss prevention programs in many countries. However, the reportedly continuing high rate of occupational noise induced hearing loss casts doubt upon the effectiveness of these standards or people's compliance with them. Moreover, the broad range of interventions included in hearing loss prevention programs makes it difficult to select the most effective strategy for reducing risk. There is a general belief that it is most effective to apply control measures in a hierarchical order. This means first using measures that eliminate the source of the noise and, at the other end of the spectrum, implementing measures that protect the individual worker only. In occupational hygiene terms this is called the hierarchy of controls (Ellenbecker, 1996). Interventions to reduce noise at the source such as efficient design, retrofit, and maintenance of equipment or special marks for extra quiet equipment are presented in the literature but these have not been evaluated nor sufficiently implemented (Seixas et al, 2001; Suter, 2002; Trabeau et al, 2008).

Despite the general belief that this should be the leading principle for noise reduction strategies in the workplace, in many situations the first attempt to reduce noise will be the provision of hearing protectors. In cases where communication and sound localization are of

vital importance for the workers, personal hearing protection devices can degrade those abilities. The use of personal hearing protection also causes other problems such as hygiene problems or occlusion effects (Suter 2002). The effectiveness of interventions to promote the use of hearing protectors has been studied in another Cochrane review (El Dib et al, 2012).

A more general and non-systematic review on the effectiveness of hearing conservation programs concluded in 1995 that there was no convincing evidence that hearing loss prevention programs are effective (Dobie, 1995). A systematic review of studies that have evaluated interventions to reduce occupational exposure to noise or to decrease occupationally induced hearing loss is therefore warranted.

Therefore, we wanted to assess the effectiveness of non-pharmaceutical interventions for preventing occupational noise exposure and occupational hearing loss compared to no or alternative interventions.

Methods

Inclusion criteria

We included the following study designs: randomized controlled trials, cluster-randomized trials, controlled before-after studies, and interrupted time-series. Evaluations of hearing loss prevention interventions can be biased by factors that also cause hearing loss other than noise, such as ageing or exposure to ototoxic substances (Kirchner et al, 2012). Randomization is the best protection against such bias. However, noise reduction is an intervention that is almost never carried out only at the individual level. As randomization is difficult to perform for the interventions of interest in this review, we also included controlled before-after studies (CBAs) and interrupted time-series (ITS) which are defined as studies in which the outcome has been measured at least three times before, and three times after, the intervention (Ramsay et al, 2003).

We included studies with male and female workers at workplaces exposed to noise levels of more than 80 dB (A) as a time-weighted average (TWA) over a period of an entire work shift or working day or part of the work shift.

We included interventions consisting of one or more of the following elements:

- 1. Engineering controls: Reducing or eliminating the source of the noise, changing materials, processes or workplace layout (Cohen et al, 1997);
- **2.** Administrative controls: Changing work practices, management policies or worker behavior (Cohen et al, 1997);
- **3.** Personal noise protection devices (NIOSH 1998);
- **4.** Hearing surveillance: Monitoring the hearing levels of exposed workers (NIOSH 1998).

We excluded all clinical interventions such as the use of anti-oxidants, magnesium, or other compounds.

Hearing loss prevention programs aim to prevent permanent threshold shifts (PTS), considered long-term effects, which only occur after several years and which can possibly be prevented by implementing engineering or administrative control measures or by consistently using protective equipment. Because of the considerable uncertainties regarding the use of otoacoustic emissions (OAE) we decided to exclude OAEs as outcome measures (European Agency for Safety and Health at WORK, 2009; Helleman et al, 2010).

The relation between exposure to noise at work and noise-induced hearing loss has been well established (ISO 1990; Prince et al, 1997). It can be safely assumed that interventions that reduce noise exposure will in turn lead to a decrease in hearing loss. Noise exposure levels are therefore a good estimate of the eventual health outcome. Although we intended to include only noise measurements executed according to a written national or international standard, in which information on measurement method, time weighting etc. was given, this turned out to be an excessively strict criterion. We therefore included all reported noise measurements. In the USA, the integration of noise levels over time is different from that in Europe with an 'exchange rate' of 5 and 3 dB respectively. We found it impossible to correct for these differences and therefore used the outcome measurements as described by the authors.

We also included noise-induced hearing loss as an outcome measure. We intended to include only hearing loss measured with a calibrated audiometer and defined by means of a written protocol, which was the case for most studies. However, in some cases this was found to be an excessively strict criterion so we also included audiometric measurements when there was no written protocol reported.

We made a distinction between immediate effects and long-term effects of interventions. Immediate effects were considered if a change in outcome was possible after, at most, eight hours. We have reported immediate effects in the original review but do not report them here. For the long-term effects we considered three follow-up times as important: less than one year, one to five years, and more than five years.

Search methods

We conducted systematic searches in the Cochrane Central Register of Controlled Trials, PubMed, Embase, CINAHL, and a number of smaller databases up to 25 January 2012. We used no restrictions on language, publication year or publication status. We modeled subject strategies for other databases on the search strategy designed for CENTRAL. The full search strategies for all databases are reported in the original Cochrane review. We scanned reference lists of identified studies and other systematic reviews for further papers.

Data collection and analysis

Pairs of the authors (EK, JV, TM, WD, CM) independently scanned the titles and abstracts and excluded those not deemed relevant. Full articles were retrieved of the other references to assess if these met our inclusion criteria. For each study included, again pairs of the review authors extracted data and assessed risk of bias independently. Where possible, we resolved discrepancies by discussion, otherwise we involved a third author. We used the items on internal validity of the checklist developed by Downs and Black for the evaluation

of the risk of bias for RCTs and CBAs (Downs and Black, 1998). We defined high quality as a score of more than 50% on the internal validity scale of the checklist. For interrupted timeseries we used the quality criteria as presented by Ramsay et al (2003).

The effect of an intervention on noise exposure over time, was calculated by subtracting the level after the intervention from the level measured before the intervention.

For hearing loss, effects were measured both as permanent loss of hearing acuity (dB units) on a continuous scale expressed as differences in means, and as the rate of workers with a certain amount of hearing loss (significant threshold shift (STS)) which was expressed using odds ratios (Rabinowitz et al, 2007). Even though the definitions of STS differed between studies, (Lee-Feldstein, 1993; Davies et al, 2008; Nilsson & Lindgren, 1980; Muhr et al, 2006) we considered them all as a similar measure of the intervention effect. We used the change in hearing level at 4 kHz as the effect measure because this frequency is generally considered to be the most susceptible to noise (May, 2000). We took the last minus the first measurement in all cases, thus a positive number indicates an increase in hearing loss.

For time-series, data from the original papers (Joy & Middendorf, 2007) were extracted or additional data were obtained from the authors (Rabinowitz et al, 2011) and re-analysed according to the recommended methods for analysis of ITS designs for inclusion in systematic reviews (Ramsay et al, 2003). This resulted in an effect estimate for an immediate change in noise levels after the intervention and an estimate for the change in trend over time after the intervention.

There were three studies (Adera et al, 2000; Lee-Feldstein, 1993; Simpson et al, 1994) that used a cluster of companies as a control group but that did not correct for the clustering effect and thus had artificially high precision. We adjusted the size of the control groups for the design effect according to the *Cochrane Handbook* based on an assumed intra-class correlation coefficient of 0.06 (Higgins & Green, 2011; Martinson et al, 1999). This was not possible for another study (Seixas et al, 2011). One study had multiple intervention arms (Hager et al, 1982) and we chose to include the arm with the most active intervention to avoid to include the same control group twice. In two other studies, we split the control group over multiple subgroups for the same reason (Muhr et al, 2006; Seixas et al, 2011). In two cases we calculated standard deviations (SDs) from P values (Hager et al, 1982) and standard errors (SE) from OR and 95% confidence interval values (Berg et al, 2009).

We assessed whether studies were sufficiently homogeneous to be included in one comparison. We tested for statistical heterogeneity by means of the I² statistic as presented in the meta-analysis graphs generated by the RevMan software (RevMan, 2011). If this test statistic was greater than 50% we considered there to be substantial heterogeneity between studies.

Since there were no comparisons for which we could include more than five studies, we did not attempt to assess publication bias.

Data synthesis

We synthesized studies that were deemed sufficiently homogeneous with regard to interventions, participants, settings, and the outcomes in a meta-analysis. For hearing loss prevention programs, we deemed both the change in hearing loss at 4 kHz and the significant threshold shift sufficiently similar to combine. Because one is a continuous measure and the other a dichotomous measure we recalculated all outcomes into effect sizes to be able to combine these two (Chinn, 2000). After meta-analysis, we transformed the pooled effect size back into a mean difference using the median standard deviation of the included studies in the formula: (pooled mean difference = pooled effect size × median standard deviation).

Some authors reported the results according to hearing thresholds at the start of the study or to gender (Pell, 1973; Adera et al, 2000). We included these categories as subgroups and combined them in the meta-analysis as subcategories.

Finally, we used the grades of recommendation, assessment, development, and evaluation (GRADE) approach to rate the quality of evidence based on the study design, risk of bias, consistency, directness, precision of results and publication bias across all studies for a particular outcome (Guyatt et al, 2010). The overall quality is considered to be high when RCTs with low risk of bias, with consistent, precise, and directly applicable results and without evidence of publication bias, measure the results for the outcome. The quality level is reduced by a level for each of the factors not met. For observational studies, the overall quality is considered low quality and this can be upgraded if the studies have special strengths or downgraded if the studies have important limitations.

For high quality evidence, it is unlikely that further research will change our confidence in the estimate of effect. For moderate quality evidence, further research is likely to have an impact and may change the estimates. For low quality evidence, further research is very likely to have an important impact and for very low quality evidence any estimate of effect is very uncertain.

We conducted a sensitivity analysis which involved leaving out one study (Pell, 1973) which had the highest risk of bias, due to differences in age between the intervention and the control group.

Results

Results of the search

Our search yielded 2491 references (1360 in 2009, plus 1129 in 2012). The screening of references for eligibility resulted in 104 full-text articles in 2009 and another 50 in 2012. Of these, 25 articles ultimately fulfilled our inclusion criteria. One article described two trials and two articles described the same study. This resulted in 25 included studies in the original review of which six were on the immediate effects of interventions. Therefore, in this article, we use the results of 19 studies on the long-term effects.

Included studies

See Table 1 with characteristics of included studies.

Two studies used a randomized design (Berg et al, 2009; Seixas et al, 2011) and two studies used an interrupted time-series (ITS) design (Joy & Middendorf, 2007; Rabinowitz et al, 2011). All remaining studies used a form of controlled before-after design.

Six studies implicitly used an equivalence design in which they tried to prove that the intervention (a hearing loss prevention program) leads to the same amount of hearing loss as in a non-exposed control group (Davies et al, 2008; Gosztonyi, 1975; Hager et al, 1982; Lee-Feldstein, 1993; Muhr et al, 2006; Pell, 1973).

In another five studies, the authors tried to show that better implementation of a hearing loss prevention program led to a better outcome (Adera et al, 1993, 2000; Simpson et al, 1994; Brink et al, 2002; Heyer et al, 2011).

All but three studies were retrospective by design meaning that the data were already gathered before the study was planned (Pell, 1973; Seixas et al, 2011; Berg et al, 2009).

Sample sizes ranged from 43 to 22 376 workers, amounting to a total of 82 794 with an average of 4870 participants per study. After adjustment for the cluster effect the sample sizes totaled 54 549 with an average of 3209 participants per study.

The legislation evaluation study (Joy, 2007) was carried out in coal mines and the administrative control intervention study (Seixas et al, 2011) in construction sites in the USA.

Seven long-term evaluation studies were published after 2000, five in the 1990s, one in the 1980s, and two in the 1970s. Thirteen of the HLPP evaluation studies were carried out in the USA, one in Canada (Davies et al, 2008), and one in Sweden (Muhr et al, 2006).

Two older studies were carried out by in-company occupational health professionals (Gosztonyi, 1975; Pell, 1973) and three by in-company military officials (Adera et al, 1993; Meyer & Wirth, 1993; Muhr et al, 2006). This created, in our view, a potential conflict of interest in the sense that the firms of the authors could potentially benefit from a positive result of their study.

The participants in all studies were described as being exposed to noise at work. However, these descriptions were often based on measurement methods that were not clearly described.

We found one study that evaluated technical noise reduction measures over time based on the change of legislation that forced coal mines to take measures to decrease noise levels (Joy & Middendorf, 2007). The new legislation established the primacy of engineering and administrative controls and an Action Level of 85 dB(A) at which enrolment for hearing conservation programs should be started. Another study intended to change workers' behavior (Seixas et al, 2011). The intervention consisted of two types of information and the distribution of personal noise level indicators. In two studies the long-term effects of using

earmuffs were compared to using earplugs (Erlandsson et al, 1980; Nilsson & Lindgren, 1980). In fifteen studies a hearing surveillance, hearing conservation, or hearing loss prevention program was evaluated as the intervention of interest. The contents of the interventions were not always clear. In Meyer 1993 the intervention was frequent follow-up during one year after a standard threshold shift had been found in a person exposed to noise, with the aim of detecting susceptible persons with increasing hearing loss. Whereas Reynolds et al (1990) evaluated the effectiveness of a hearing loss prevention program for workers on 12-hour work shifts compared to normal shifts.

In all but one study, the authors measured hearing loss but its definition varied. In Seixas et al (2011), the authors used personal noise dosimeters to measure the sound pressure level as full-shift L_{eq} with 3-dB exchange rate, 80 dB(A) threshold, 85 dB(A) criterion level, and slow response. In the ITS studies, one study measured the noise exposure as eight-hour TWA exposure (Joy & Middendorf, 2007) and the second study used the rate of hearing loss in the binaural average hearing level at 2, 3, and 4 kHz (Rabinowitz et al, 2011).

Studies were excluded because they were either not empirical studies or because the authors did not use a control group. One controlled study on noise reduction in an MRI scanner was excluded because only the patients were exposed to the noise and not the healthcare workers (Mechfske et al, 2002). Other studies of noise reduction in occupational settings were either case studies (Jelinic et al, 2005; Knothe & Busche, 1999; Pingle & Shanbag, 2006; Scannell, 1998; Stone et al, 1971) or had a cross-sectional design without pre-intervention measurements (Chou, 2009), or consisted of descriptions of a noise abatement strategy but without a control group (Groothoff, 1999), or recommended noise reductions without evaluating them (Bowes & Corn, 1990; Golmohammadi et al, 2010; Kardous et al, 2003).

Risk of bias in included studies

The overview of risk of bias is shown in Figure 1. Most studies scored poorly on all aspects of the checklist.

One of the two ITS studies met three of the seven risk of bias criteria which means that there was considerable risk of bias in the study (Joy & Middendorf, 2007). The most serious risk of bias was that the intervention and the outcome measurements were not independent. The number of inspections on which the noise measurement data is based increased after the intervention and might also have included workplaces with lower noise levels that were not previously included. The other ITS study met five of the seven criteria and thus we judged it to have a low risk of bias overall (Rabinowitz et al, 2011).

Two studies achieved more than 50% of the maximum score of 13 on the internal validity scale of the checklist and were considered high quality (Muhr et al, 2006; Berg et al, 2009). None of the studies used blinded outcome assessment.

For long-term evaluation, particularly in studies that used non-exposed workers as the control group, the age and hearing loss of the intervention and control group participants should be comparable at baseline. Comparability of both age and hearing loss at baseline could be ascertained in four studies (Davies et al, 2008; Lee-Feldstein, 1993; Muhr et al,

2006; Heyer et al, 2011), age only in two studies (Gosztonyi, 1975; Berg et al, 2009), and hearing loss only in one study (Pell, 1973), and neither age nor hearing loss in one study (Hager et al, 1982). In Pell (1973) there was a difference of ten years between the protected and the non-exposed group, artificially increasing the risk in the non-exposed group. In Hager et al (1982) there was a 7.8 dB difference in hearing level at entry to the study between the protected and non-exposed group, thus artificially increasing the risk in the protected group. In Pell (1973) and Lee-Feldstein (1993) the non-exposed group still had considerable exposure and could thus have confounded an effect of the intervention program. Thus, according to our judgment, only three long-term evaluation studies had a low risk of bias.

We did not formally test for reporting bias. However as many authors had an interest in reporting favorable results we considered it conceivable that the results of the studies are biased towards a positive outcome.

Effects of interventions

Engineering controls, legislation—We found no studies that evaluated the effect of engineering controls for decreasing noise levels, except for one study that indirectly measured the effect of legislation on the decrease of noise levels. We assumed that the effect was mediated by better engineering controls. In the Joy and Middendorf (2007) study, in which legislation was introduced to reduce noise levels in the mining industry, the immediate effect of introducing changes in the year 2000 was a 27.7 dB reduction in the median noise level (95% confidence interval (CI) –36.1 to –19.3 dB) compared to that predicted by extrapolation of the pre-intervention slope. The long-term effect in the change of trend in time as measured by the change in slope before and after the intervention was –2.1 dB/year but this was not statistically significant (95% CI – 4.9 to 0.7 dB). For the underground mining noise levels the immediate effect was –16.8 dB (95% CI – 23.5 to –10.1 dB) and the long-term effect was –3.8 dB/year (95% CI – 6.2 to –1.4 dB). If we took 1999 as the year in which the change of legislation was implemented, the immediate effect was smaller but the change of slope larger and significant. We rated the overall quality of evidence as low.

Personal hearing protection devices

Earmuffs versus earplugs (three-year follow-up) (CBA)—Workers were divided into high noise exposure and low noise exposure. In the meta-analysis, the OR of sustaining a STS for the muff-wearing workers versus the plug-wearing workers was estimated at 0.8 (95% CI 0.63 to 1.03) for those in high noise levels and at 2.65 (95% CI 0.40 to 17.52) for those in low noise levels (Erlandsson et al, 1980; Nilsson & Lindgren, 1980). The results from the low noise group were not homogenous. The overall quality of evidence was rated as very low.

Hearing loss prevention programmes

Hearing loss prevention program versus audiometric testing only, effect on hearing loss—In Berg et al (2009) the likelihood of developing an STS after three-year and 16-year follow-up was similar for the intervention and control group with an odds ratio

of 0.85 (95% CI 0.29 to 2.44) after three years follow-up, and 0.94 (95% CI 0.46 to 1.91) after 16 years follow-up

Hearing loss prevention program with daily noise exposure monitoring and feedback versus audiometric testing only, effect on hearing loss—In

Rabinowitz et al (2011) there was no effect of the program immediately after introduction. The trend over time showed a significant yearly decrease of the rate of hearing loss of -1.57 dB (95% CI -2.37 to -0.77) in the intervention group. Similar but smaller improvements over time occurred also in the control group (-0.23 dB per year with 95% CI -0.39 to -0.07). The trend of the difference between the intervention and control group remained significant with -1.35 dB per year for the intervention group (95% CI -2.09 to -0.61). The authors could also control for the initial rate of hearing loss as a potential confounder. The results were similar as in the previous comparison but the trend over time for the intervention group minus the control group was no longer significant (-0.82 with 95% CI -1.86 to 0.22). The authors also analysed the data as the mean yearly change in rate of hearing loss before and after the introduction of the intervention but their results were similar to our findings.

Hearing loss prevention training with noise level indicators versus training only, effect on noise—In Seixas et al (2011), we compared the change in noise level of two intervention groups to one control group. The comparison was basic information plus extensive information in so called tool-box sessions, plus personal noise-level indicators or basic information plus personal noise level indicators versus basic information only. We entered the two interventions as subgroups in one comparison. Noise level indicators with or without information did not show a significant effect in lowering the sound pressure level compared to the group receiving information only. At two months, the noise level decreased 0.32 dB more in the control group (95% CI – 2.44, 3.08) but at four months follow-up the noise levels in the intervention group decreased 0.14 dB more than in the control group (95% CI – 2.66 to 2.38) but neither were statistically significant.

Extensive information versus information only, effect on noise—In the same study (Seixas et al, 2011), noise levels of workers that received additional extensive information in four tool-box sessions were compared to those of workers that received one baseline information session only but there were no significant differences. The noise level decreased 1.7 dB more in the information only control group at two months (95% CI – 1.24 to 4.64) but 0.3 dB less at four months (95% CI –2.31, 2.91) compared to the intervention group.

Well-implemented hearing loss prevention program (HLPP) versus less well-implemented HLPP, effects on hearing loss, long term follow-up—In Simpson et al, 1994, employees in companies with a well-implemented HLPP ran a lower risk of STS than those in companies with less well-implemented programs, with a relative risk of 0.36, which was not significant (95% CI 0.09 to 1.42).

Well-implemented hearing loss prevention program versus less wellimplemented hearing loss prevention program, effects on hearing loss, very

long-term follow-up—In the meta-analysis of three studies the effect was estimated as the odds ratio of sustaining a STS during the follow-up period in workers in companies with a well-implemented HLPP versus those in companies with less well-implemented programs (Adera et al, 1993, 2000; Brink et al, 2002). The odds ratio (OR) of sustaining a STS was 0.40 (95% CI 0.23 to 0.69) for workers covered by well-implemented programs. The results were statistically heterogeneous, with an I² of 66%. We rated the overall quality of evidence as low. In Heyer et al (2011), only one out of three quality aspects of the hearing loss prevention program was associated with hearing loss. We could not include the data in a meta-analysis because they were reported as the results of a regression analysis. Years with more than 50% use of hearing protection devices (better quality) caused less hearing loss than years in a hearing loss prevention program with less than 50% compliance of using hearing protection devices, for men with a beta of -0.31 dB(A) (95% CI -0.37 to -0.24)) and for women $-0.14 \, \mathrm{dB(A)}$ (95% CI $-0.27 \, \mathrm{to} -0.01$). The other quality aspect, noise monitoring (men: beta -0.13 dB(A) (95% CI -0.20 to -0.07); women: beta -0.15 dB(A) (95% CI –0.44 to 0.14) showed varying results but was, according to the authors likely to be confounded by plant. The quality aspects of audiometric testing (men: beta 0.13 dB(A) (95% CI 0.06 to 0.19); women: beta 0.33 dB(A) (95% CI 0.19 to 0.47), and worker training (men: beta -0.04 dB(A) (95% CI -0.10 to 0.02); women: beta -0.05 dB(A) (95% CI -0.18 to 0.02); 0.07), did not show a significant association with hearing loss.

Hearing loss prevention program or hearing protection versus non-exposed workers, effects on hearing loss, long-term follow-UP—In Muhr et al (2006) the risk ratio of sustaining a standard threshold shift (STS) in the total cohort of recruits was 3.0 (95% CI 1.1 to 8.0) compared to recruits waiting for their training and not exposed. The risk increased with the level of exposure to 4.0 at the highest level of exposure (95% CI 1.0 to 16.0).

Hearing loss prevention program or hearing protection versus non-exposed workers, effect on hearing loss, very long-term follow-up—In the meta-analysis of four studies the summary effect size estimate was 0.05 (95% CI – 0.05 to 0.16). When calculated back to a difference in mean changes in hearing level at 4 kHz the result was 0.53 dB (95% CI – 0.53 to 1.68) (Gosztonyi, 1975; Hager et al, 1982; Lee-Feldstein, 1993; Pell, 1973). The results were statistically homogeneous. We performed a sensitivity analysis by leaving out the study by Pell (1973) because of the 10-year age difference between the intervention and the non-exposed group, which could explain a difference of 7 dB in hearing thresholds (calculated based on ISO 1990). This yielded an effect size of 0.17 (95% CI – 0.06 to 0.40). When calculated back to a difference in mean changes in hearing level at 4 kHz, this resulted in 1.8 dB (95% CI – 0.6 to 4.2).

These results indicate that the workers in a hearing loss prevention program have similar hearing thresholds as the non-exposed workers. However, the 95% confidence interval includes the possibility of a hearing loss as great as 4.2 dB. This threshold is equivalent to thresholds resulting from five years of exposure to 85 dB(A). Consequently these results do not rule out the risk of hearing loss in protected workers.

Davies 2008 measured the time to a STS and compared the hazard ratio (HR) to a non-exposed group with a result of 2.1 (95% CI 1.3 to 3.5) for workers with exposure of 80 to 85 dB-years. The HR gradually increased to 6.6 (95% CI 5.6 to 7.8) for workers with an exposure of more than 100 dB-years. Combined in the meta-analysis, this yielded a HR of 3.8 (95% CI 2.7 to 5.3). We rated the overall quality of evidence as very low.

Follow-up examinations after sts versus no follow up in one year, effects on hearing loss, one-year follow-up—In one study the OR for sustaining a STS was 0.87 (95% CI 0.56 to 1.36) after having a year of follow-up examinations versus no examinations (Meyer & Wirth, 1993).

Hearing loss prevention program for 12-hour shifts versus eight-hour shifts, effects on hearing loss, one-year follow-up—In one study the mean difference in change in hearing level over one year at 4 kHz between the 12-hour shift and 8-hour shift was -0.68 dB (95% CI -1.85 to 0.49) (Reynolds et al, 1990a).

Discussion

We found low quality evidence from one study which showed that legislation can probably induce technical improvements in the working environment that lead to a measurable reduction in noise exposure levels.

Very low quality evidence of long-term evaluation studies of components of hearing loss prevention programs showed that the use of hearing protection devices in well-implemented HLPP was associated with less hearing loss. The studies that evaluated earmuffs versus earplugs also showed that, in high noise levels, earmuffs probably perform better than earplugs and vice versa for low noise levels. This could not be shown for other elements of hearing loss prevention programs such as worker training, audiometry alone, or noise monitoring. More individual information on daily noise exposure as part of a hearing loss prevention program showed favorable but non-significant effects both for hearing loss and for daily noise-exposure levels.

There was also very low quality evidence that compared to non-exposed workers in long-term follow-up average hearing loss prevention programs do not reduce the risk of hearing loss to below a level at least equivalent to that of workers who are exposed to 85 dB(A) The mean hearing loss for this exposure would be about 4.2 dB (ISO, 1990; Hozo et al, 2005; Piaggio et al, 2006) which is still in the 95% confidence interval that we found. In addition, two other studies that could not be combined in the meta-analysis still found considerable risks of hearing loss in spite of participants being covered by a hearing loss prevention program.

Overall completeness and applicability of evidence

It is striking that only one controlled study evaluated measures to reduce noise exposure at the macro-level. We could not find any controlled studies in which technical measures to reduce noise levels were evaluated at the company level. Other studies on technical noise reduction that we found but did not include were mostly case studies which showed

considerable reductions in noise level due to different interventions. Glasziou et al (2007) argues that in such cases no controlled studies are necessary. On the other hand, the measurement of noise levels in real working life is not simple and can be biased by many factors such as the worker, the task, and the environment where it is impossible to control all operational and environmental variables. Comparing before and after measurements without a control condition can, therefore, be easily misleading. It is also unclear whether the noise levels in the immediate surroundings of machinery also lead to a reduction in the personal noise doses received by workers, and whether such interventions are maintained in the long run. That is why we believe that more and better efforts should be made to use study designs with greater validity, such as a series of measurements before and after the interventions or a controlled-before-after measurement design.

No studies evaluated the effectiveness of the practice of recommendations from occupational health services, national agencies or occupational health professionals to reduce noise levels. A possible but speculative reason for the low number of studies could be the tight regulation regarding noise at work which makes it difficult to challenge current practice in experiments.

Even though all the studies intended to evaluate a hearing loss prevention program those programs were not clearly defined. It is also unclear if the results are applicable in other settings and if measures to reduce noise levels were taken or if workers got training and education in addition to providing hearing protection devices. Two studies used a randomized design. One was conducted in the construction industry. It shows that, even though it has often been argued that it is difficult to randomize workers, this is feasible even in difficult sectors as the construction industry (Seixas et al, 2011). There were two studies that offered a novel component of a HLPP: monitoring personal noise exposure in a way that the individual worker is made aware of his exposure levels (Rabinowitz et al, 2011; Seixas et al, 2011). Probably due to small sample sizes neither of them found a significant outcome but given the problems in construction industry with varying noise sources, this could be a promising intervention to be tested further in this branch of industry.

Quality of the evidence

The risk of bias was high because studies did not very well control for the confounding effect of aging and prior hearing loss and most studies were set up retrospectively. Thus there is a need for better quality studies such as a randomized controlled trial. Also the interrupted time-series design has potential for evaluating hearing loss prevention programs because much data is collected routinely. We believe that these studies would provide better quality evidence than comparing hearing loss prevention programs to non-exposed workers or using a retrospective design.

There was also a lack of information on the implementation level of the prevention measures. This is especially important in the studies that compared well-implemented hearing loss prevention programs with those of poorer quality. It is possible to compare different hearing loss prevention programs or single program components, or different levels of implementation in a cluster-randomized design. This would eventually yield much higher

quality information on the effectiveness of hearing loss prevention. Given the numbers of hearing-impaired workers, this effort seems justified.

Potential biases in the review process

Even though we did our best to search databases that would contain grey literature, such as NIOSHTIC, we did not have the opportunity to go through all conference proceedings. It is therefore possible that we missed retrospective cohort studies. Publication bias could play a role in the results of the hearing loss prevention program studies, with four of the studies being funded or carried out by professionals that were part of the company, who could possibly have an interest in publishing studies demonstrating a preventative effect of hearing-loss prevention programs.

Agreements and disagreements with other studies or reviews

One other review concluded that the available evidence from long-term evaluation studies does not support the effectiveness of hearing loss prevention programs (Dobie, 1995). The author acknowledges that he did not perform a systematic search. He included and commented upon both evaluation studies that compared hearing protection users versus nonusers and those that compared protected workers to non-exposed workers. He included three long-term evaluation studies, of which two were also included in this review, and of which one was excluded. His conclusions are similar to ours in that the evidence for the effectiveness of hearing loss prevention programs is not very convincing. Borchgrevink (2003) reviewed only occupational noise-induced hearing loss data and because hearing loss still occurred he concluded that hearing loss prevention programs were ineffective. Daniell et al (2006) evaluated the quality of hearing loss prevention programs in companies and concluded that they were commonly incomplete and that consideration of noise control was low in all industries. This concurs with the conclusions of our review. Another narrative review was directed at one sector only (mining) (McBride, 2004), but drew similar conclusions.

Implications for practice

There is one study that shows that legislation can reduce noise exposure levels at the branch level. Technical measures can yield dramatic reductions in noise levels but there are, however, no controlled evaluation studies on implemented technical measures to reduce noise levels in companies, nor on advice to take such measures. Technical measures, therefore, should be the first choice in the management of noise problems at work, especially if the noise reductions lead to a reduction in personal noise doses received by workers. Better implementation and reinforcement of the law could be effective in better implementing technical measures for reducing noise levels.

There was very low quality evidence that the use of hearing protection devices in well-implemented HLPP was associated with less hearing loss, but this could not be shown for other elements such as worker training or audiometry alone or noise monitoring. More individual information on noise exposure as part of a hearing loss prevention program showed a favorable but non-significant effect. There was also very low quality evidence that, compared to non-exposed workers, average hearing loss prevention programs do not

reduce the risk of hearing loss to below a level at least equivalent to that of workers who are exposed to 85 dB(A).

Implications for research

Research on the long-term effects of technical noise reducing measures and on the effects of recommendations of measures is needed. This should preferably be done using a clusterrandomized design in which firms or departments are randomized to either the intervention or the control group. Also studies that evaluate the effects of engineering control interventions should make use of control conditions or use an interrupted time-series approach with at least three measurements before and three after the intervention. Noise measurements can be improved by taking into account the known variability in noise levels (ISO 9612:2009) and by adapting the number of measurements accordingly. Hearing loss prevention programs should also be evaluated in a cluster-randomized design, in which well implemented programs can be compared to less well implemented programs. A follow-up time of five years has been shown to be feasible and should be sufficient to show effects on hearing given the observation that hearing threshold changes at 4 kHz can already occur in the first year of exposure and can be more than 25 dB after two to five years (Sulkowski, 2007). A detailed process evaluation could reveal how well the measures were implemented. Better use of the available data of retrospective cohort studies is needed, taking into account the hearing status at the beginning of the study, differences in age, and changes in noise exposure levels over time to avoid biased results. Studies evaluating hearing loss prevention programs with innovative content are especially needed in branches of industry where noise exposure is prevalent and difficult to eliminate such as the construction industry.

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Abbreviations

CBA Controlled before-after studies

GRADE Grading of recommendations, assessment, development and evaluation

HLPP Hearing loss prevention program

ITS Interrupted time-series

RCT Randomized controlled trial
STS Significant threshold shift
TWA Time-weighted average

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+ Unplanned subgroup analysis + Adjustment for confounding -> Selection bias (population) "Incomplete outcome data ">Allocation concealment | (Selection bias (time) Blinding (outcome) | Blinding (subjects) + Outcome measures + Statistical analysis | Randomization ~ Compliance Adera, 1993 ? Adera, 2000 Berg, 2009 ? Brink, 2002 Davies, 2008 ? Erlandsson, 1980 ? Gosztonyi, 1975 + Hager, 1982 Heyer, 2011 ? Lee-Feldstein, ? 1993 Meyer,1993 ? Muhr, 2006 + Nilsson, 1980 ? Pell, 1973 ? Reynolds, 1990 ? Seixas, 2011

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?

Figure 1. Risk of bias in the included studies: += low risk; ?= unclear risk; -= high risk.

Simpson, 1994

Author Manuscript

Table 1

Characteristics of included studies (n = 19).

| Study | Design | Participants | Interventions | Outcomes | Notes |
|------------------|-------------------------------------|---|---|---|--|
| Adera, 1993 | Controlled before-after study | Various occupations; n = 692; US, military | Intervention: HLPP in company with apparently good programme (1972 to 1981); n = 93. Comparison: HLPP in study company (1980 to 1989) with poor programme; n = 599 | STS/100 person-years greater or equal than 10 dB in either ear as the mean change at 2, 3, and 4 kHz; Nine-year follow-up | Comparability: Age: adjusted Hearing: ? |
| Adera, 2000 | Controlled before-after study | Various occupations; n = 19 640; US, one company | Intervention: well-implemented HLPP in five companies; n = 4317, after adjustment for design n = 22 Comparison: HLPP in one company with poor quality HLPP; n = 15 323 | STS/100 person-years greater or equal than 10 dB in either ear as the mean change at 2, 3, and 4 kHz; Five-year follow-up | Comparability: Age: adjusted Hearing: adjusted |
| Berg, 2009 | Cluster randomized controlled study | Agricultural students involved in farm work; n = 753; US, 34 schools | Intervention: hearing test yearly, instruction once, 11 mailings at home, free hearing protection plus replacements, use of sound meter Control: yearly hearing tests plus questionnaires | STS with 10 dB or greater loss at 2, 3, 4 kHz in either ear, median and mean thresholds at 0.5, 1, 2, 3, 4, 5 6 kHz, nigh-frequency average (3, 4, 6 kHz) and low-frequency average (0.5, 1, 2 kHz) thresholds; bulge depth Three-year and 16-year follow-up | Comparability: Age: Intervention mean 14.5 years; control mean 14.6 years Hearing: max. threshold (R or L) at 0.5 kHz Intervention median 10 dB/ Control median 5 dB, at 1, 2, 3, 4 kHz. Intervention/Control median 5 dB, at 6 kHz. Intervention median 15 dB/ Control median 10 dB |
| Brink, 2002 | Controlled before-after study | Automobile workers; n = 264; US, one automobile company | Intervention: wearing hearing protection > 33% of the time; n = 132 Control: wearing hearing protection < 33% of the time; n = 132 | Hearing thresholds at 0.5, 1, 2, 3, 4 kHz 14-year follow-up | Comparability: Age: ? Hearing: ? |
| Davies, 2008 | Controlled before-after study | Workers in lumber mills during 1979–1996 who had at least two hearing tests; n = 22 376; Canada, British Columbia | Intervention: hearing conservation programme; n = 16 347 Control: those exposed to less than 80 dB-years plus those at their first hearing test following baseline; n = 6002 estimated from the number of person-years of 41 357 with 6.8-year follow-up | STS: 10 dB or greater at 2, 3 or 4 kHz in the better ear | Comparability: Proportional hazards model to adjust for age and hearing ability at baseline |
| Erlandsson, 1980 | Controlled before-after study | Shipyard workers; n = 40; Assembly department n = 26 less than 89 dB(A) exposure n = 26; Boiler department n = 24 more than 89 dB(A) exposure n = 24; Sweden, one shipyard | Intervention: those wearing earmuffs; n = 20 Control: those wearing earplugs; n = 30 | Average change in hearing thresholds over three years at 2, 3, 4, 6, 8 kHz Three-year follow-up | Comparability: Age: matched Hearing: ? |
| Gosztonyi, 1975 | Controlled before-after study | Various occupations in one company; $n = 142$; US | Intervention: HLPP, $n = 71$ Control: non-exposed workers; $n = 71$ | Average change in hearing thresholds over 3 years at 0.5, 1, 2, 3, 4, 6 kHz | Comparability: |

| Study | Design | Participants | Interventions | Outcomes | Notes |
|---------------------|---|---|---|--|---|
| | | | | Five-year follow-up | Age: Intervention - mean 42.8 years; Control - mean 43.2 years Hearing: ? |
| Hager, 1982 | Controlled before-after study | Various workers; n = 43; US, one company | Intervention: hearing protection as part of HLPP in company; n = 27 Control: non-exposed colleagues; n = 16 | Hearing thresholds at entrance minus HT at follow-up at 0.5, 1, 2, 3, 4, 6 kHz Follow-up average five and ten years | Comparability: Age:? Hearing: intervention median 8.1 dB 4 kHz; control median 0.3 dB 4 kHz |
| Heyer, 2011 | Controlled before-after study (retrospective) | Workers of two automotive plants, one food-processing plant; n = 6483; US | HLPP: 1. Training and education, 2. Noise monitoring, 3 Engineering and administrative controls, 4. Audiometric testing and surveillance, 5. Medical referral, 6. HPD use, 7. Administrative and record keeping procedures. Intervention: years in better implemented programme based on more HPD use, better training, better noise monitoring, better audiometry. Control; years in less well implemented programme based on same criteria | Rate of hearing loss increase over 3, 4, 6 kHz both ears between the first and subsequent audiograms | Comparability: Age and Hearing: adjusted Noise exposure: adjusted, based on retrospective noise level assessment |
| Joy, 2007 | Interrupted time-series | Coal mines; Workplace measurements; n = 142,735; US, whole mining branch | Introduction of new legislation in 1999 becoming effective in 2000: primacy of engineering and administrative controls, establishment of an Action Level of 85 dB(A), hearing conservation programme enrolment starting from 85 dB(A); introduction of statutory hearing loss of 25 dB average over 2, 3 and 4 kHz in either ear | Median of measurements of compliance with Permissible Exposure Level which includes all sound pressure levels from 90 dB(A) to 140 dB(A) with a doubling rate of 5 dB as an eight-hour time weighted average | See Cochrane Review for data |
| Lee-Feldstein, 1993 | Controlled before-after study | Automobile workers; n = 11 435; US, one company | Intervention: HLPP: $n = 11\ 104$, after cluster adjustment $n = 97$ Control: non-exposed colleagues; $n = 331$ | Rate of STS, average change in mean hearing threshold at 2, 3 and 4 kHz in the worst ear Follow-up average five years | Comparability: Age: adjusted Hearing: adjusted |
| Meyer, 1993 | Controlled before-after study | Various occupations; n = 1377; US, military | Intervention: detailed follow-up examination after STS; n = 496 Control: no detailed follow-up; n = 821 | Rate of new STS; before 1990 defined as a change of 20 dB or more at 1, 2, 3 or 4 kHz; after 1990 an average change of 10 dB or more at 2, 3 and 4 kHz in either ear One year follow-up | Comparability: Age: ? Hearing: ? |
| Muhr, 2006 | Controlled before-after study | Army conscripts n = 885; Exposure to impulse noise from shooting; Sweden, military | Intervention: regular hearing protection; n = 747 Control: non-exposed waiting for training period; n = 138 | STS equal to or greater than 15 dB at the best ear at any of 0.25, 0.5, 1, 2, 3, 4, 6 or 8 kHz between baseline and follow-up hearing test average follow-up of 7.5 to 11 months | Conscripted between 1 June 1999 and 1 June 2000 with < 20 dB HL over 2 and 3 kHz, and < 32.5 dB over 4 and 6 kHz, or < 25 dB over 2 and 3 kHz, and < 20 dB over 4 and 6 kHz, and < 20 dB over 4 and 6 kHz, and < 20 dB over 4 and 6 |

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| Study | Design | Participants | Interventions | Outcomes | Notes |
|------------------|--|--|---|---|--|
| Nilsson, 1980 | Controlled before-after study | Ship builders: n = 231; Highly exposed group with more than 94 dB(A); n = 1838 Low exposed group with less than 88 dB(A); n = 1354 Sweden, one shipyard | Intervention: workers wearing earmuffs; n = 1883 Control: workers wearing earplugs; n = 1309 | STS more than 10 dB any frequency in either ear per 100 person-years; frequencies tested: 0.25, 0.5, 1, 2, 3, 4, 6, 8 kHz | Comparability: Age:? Hearing: both groups < 35 dB all frequencies |
| Pell, 1973 | Controlled before-after study; Prospective | Various workers; n = 1572; n = 628 less than 20 dB HL; n = 559 15 to 35 dB HL; n = 385 > 40 dB HL; US; one company | Intervention: HLPP mainly hearing protection; n = 399 Control: non-exposed colleagues; n = 1173 | Average change in hearing thresholds last-entrance measurement at 0.5, 1, 2, 3, 4, 6 kHz Five-year follow-up | Comparability: Age: intervention - mean 34 years; control -mean 43 years Hearing: stratified according to HL at start |
| Rabinowitz, 2011 | Controlled before-after study/ interrupted time-series (authors provided additional data for ITS analysis) | Various workers of an aluminium smelter; n = 312 | Intervention: daily monitoring of atear noise exposure and regular feedback from supervisors Control: on-going hearing conservation program (regulation mandated hearing tests, noise measurements, training) | Median TWA ambient noise exposures; median and range of noise exposures inside hearing protection (intervention group); high frequency hearing threshold levels (2, 3, 4 kHz); amual rate of hearing loss (dB/year) | age, gender and hearing) Age: similar age (within 5 years; nervention mean 48.7 years; control mean 48.7 years; control man 48.6 years Hearing: controls matched (C1) and highly matched (C2): C1: baseline hearing = similar high frequency hearing threshold levels (binaural average of 2, 3 and 4 kHz) (within 5 dB) (n = 178/C 234) C2: baseline hearing and initial rate of hearing loss during pre- intervention period (n = 146/C 138) |
| Reynolds, 1990a | Controlled before-after study | Various workers; n = 852; U.S. one company in the chemical industry | Intervention: HLPP at 12-hour shifts; n = 272, adjusted for design effect n = 218 Control: HLPP at eight-hour shifts; n = 580 | Average change in hearing thresholds at 0.5, 1, 2, 3, 4, 6 kHz One-year follow-up | Comparability: Age: ? Hearing: "similar loss" |
| Seixas, 2011 | Both cluster and individually randomized RCT | Construction workers; various trades; n = 176; US | Many comparisons possible we choose to compare two interventions considered to be most relevant for practice. Intervention 1: baseline training plus noise 'tool box' onsite training (n = 44) Intervention 2: baseline training plus noise 'tool box' onsite training plus puersonal noise level indicator (n = 41) Control: baseline training plus personal noise level indicator (n = 41) | Noise level measured as L _{aeq} at two and four months follow-up | First baseline training, then cluster-randomized to tool-box; then individuals were randomised to noise level indicators or no indicators |
| Simpson, 1994 | Controlled before-after study | Various occupations in 21 companies; n = 13283; US | Intervention: well-implemented HLPP Control: poor quality HLPP | Rate of standard threshold shifts defined as on average 10 dB or more at 2, 3 and 4 kHz in either ear Follow-up average one year | Comparability: Age: ? Hearing: ? |

?: no data available; HLPP: Hearing loss prevention program.